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SCIENTIFIC OPINION

Scientific Opinion on the safety of vitamin D-enriched UV-treated baker's yeast[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of "UV-treated baker's yeast" (Lallemand SAS) as a novel food ingredient in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The novel food ingredient (NFI) is baker's yeast treated with UV irradiation to induce the conversion of ergosterol to vitamin D2. The applicant intends to use the NFI during the production of yeast-leavened bread, rolls, fine pastry and food supplements. The Panel considers that the provided compositional data, the specification, the data from batch testing, data on the stability on the production process are sufficient and do not give rise to safety concerns. The Panel concludes that the data provided are sufficient and do not give rise to safety concerns. The applicant intends to use the NFI as an alternative source of vitamin D for food supplements and for fortification of yeast-leavened bread, rolls and fine pastry at maximum concentrations of 5 µg vitamin D2 per 100 g of these foods. The applicant provided combined intake estimates for these two food categories for "all subjects" and "consumers only". The source for the production of the NFI is *Saccharomyces cerevisiae*, an organism with a long history of safe food use. Even if the NFI is used at the maximum intended use levels, which deliver 5 µg vitamin D/100 g bread, rolls and fine pastry, it is highly unlikely that Tolerable Upper Intake Levels as established by EFSA (EFSA NDA Panel, 2012) are exceeded. The Panel considers that UV-treated baker's yeast exhibiting an enhanced content of vitamin D2 is safe under the intended conditions of use.

KEY WORDS

novel food, ingredient, baker's yeast, *Saccharomyces cerevisiae*, UV, vitamin D

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[1] On request from the European Commission, Question No EFSA-Q-2013-00335, adopted on 12 December 2013.

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SUMMARY

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of "UV-treated baker's yeast" (Lallemand SAS) as a novel food ingredient in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States.

The novel food ingredient (NFI) is baker's yeast (*Saccharomyces cerevisiae*) treated with UV irradiation to induce the conversion of ergosterol to vitamin D2 (ergocalciferol). The applicant intends to use the NFI during the production of yeast-leavened bread, rolls, fine pastry and food supplements. Vitamin D2 contents in eight lots of the NFI ranged from 2 560 000 to 3 750 000 IU/100 g (640–940 µg/g); the average content of vitamin D2 in these lots was 3 065 417 IU/100 g, corresponding to 770 µg/g. The applicant performed analyses to investigate the potential formation of other sterols under the conditions employed for the UV treatment of baker's yeast. The results of high-performance liquid chromatography (HPLC) show that, apart from the intended vitamin D2, tachysterol was the only additional sterol detected via HPLC analysis. According to the applicant, the average amounts of vitamin D and tachysterol in the vitamin D2 yeast concentrate are 750 µg/g (30 000 IU) and 140 µg/g, respectively. Therefore, the production of a bread product containing 200 IU/100 g will require 6.67 mg of vitamin D2 yeast concentrate that contains 30 000 IU/g. The 6.67 mg of yeast concentrate will provide 0.93 µg of tachysterol/100 g of bread.

The Panel notes that UV irradiation may result in reactions of biomolecules, such as lipids or proteins. However, taking account of (i) the parameters of the UV treatment of baker's yeast as performed in the course of the production process of the NFI (e.g. the dimensions of the UV irradiation chamber, the flow rate of the yeast cream and the employed UV power), (ii) the low levels of potential reaction products that might be expected under these conditions from UV-induced reactions, e.g. oxidations of yeast lipids or proteins, and (iii) the intended use levels of the NFI, the Panel considers that it is not necessary to perform additional analyses for potential products formed from yeast components as a result of the UV treatment.

Stability tests of the NFI and of three types of bread baked with the NFI at 227 °C indicated that there was no significant reduction in the levels of vitamin D2 for a period of three years in the NFI and for 14 days in three bread types which were baked with the NFI. The applicant also provided data on the stability of vitamin D2 in two batches of a food supplement stored at 4 °C, 25 °C and 30 °C for 24 months. The data suggest minimal, if any, loss of vitamin D2 over this period.

The Panel considers that the provided compositional data, the specification, the data from batch testing and the stability of the NFI are sufficient and do not give rise to safety concerns.

The applicant provided information on the dimensions of the UV irradiation chamber and the electrical cabinet, the flow rate of the yeast cream and the employed UV power. The applicant did not provide information on the maximum UV irradiation power applied; however, the Panel considers the information provided by the applicant in response to the Member State comment on UV treatment conditions to be sufficient. The UV treatment step is followed by drying using a fluid bed dryer (yeast for baking) or a spray dryer or roller dryer (yeast for supplements). The resulting "vitamin D2 yeast concentrate" contains between 1 800 000 IU/100 g and 3 500 000 IU/100 g vitamin D2, compared with the initial concentration of less than 20 IU vitamin D2/100 g. When used for baking, this concentrate would be blended with conventional yeast in order to adjust the intended amount of vitamin D2 in the final product.

The Panel considers that, although the UV treatment may result in mutations in the employed baker's yeast, their low numbers, the conditions of the process and the intended uses of the NFI would not allow mutants to become dominant in the final product.

According to the applicant, the UV-treated baker's yeast retains its baking activity; however, no experimental data were provided.

The Panel concludes that the data provided on the production process are sufficient and do not give rise to safety concerns.

The applicant intends to use the NFI as an alternative source of vitamin D for food supplements and for fortification of yeast-leavened bread, rolls and fine pastry at maximum concentrations of 5 µg (200 IE) vitamin D2 per 100 g of these foods. The applicant used the chronic food consumption statistics of the EFSA Comprehensive Food Consumption Database to estimate potential intakes. Because this database does not include "yeast-leavened fine pastry", the applicant conservatively estimated intakes for the broader, superordinate level 2 category "fine bakery wares". "Rolls" are covered by the level 2 food category "bread and rolls" in the published chronic food consumption statistics of the EFSA Comprehensive Food Consumption Database. The applicant provided combined intake estimates for these two food categories for "all subjects" and "consumers only". The highest 97.5th percentile consumption for "consumers only" among EU Member States was obtained for "other children" (4-10 years; 27.2 µg/day) and adults (36.0 µg/day) from Latvia and for adolescents from Germany (35.5 µg/day).

According to EFSA's opinion on upper levels for vitamin D from 2012, high percentile intakes of vitamin D from the diet of young children, adolescents and adults vary from 2.4 to 11.9, from 3.0 to 7.7 and from 2.4 to 16.9 µg/day respectively.

Regarding food supplements, the applicant considers the use of the NFI in food supplements as a direct "like for like" replacement for existing vitamin D2 ingredients and, as such, will it not significantly add to the level of vitamin D consumed by individuals via supplements. The use level of the NFI intended by the applicant for food supplements is 5 µg/day.

The Panel notes that the type of intake estimate provided by the applicant assumes that all consumed food products within a food category contain the ingredient at the maximum specified level of use. It is also noted that the combined high percentile intake from the two level 2 food categories ("breads and rolls" and "fine bakery wares") based on summary statistics is expected to over-estimate intakes. Third, among the level 2 food category "fine bakery wares" the applicant intends to use the NFI only in "yeast-leavened fine pastry", but the intake estimate is based on intakes for the complete level 2 category "fine bakery wares", although many products in this category do not contain yeasts. The Panel therefore considers that the applicant's intake estimate significantly over-estimates intakes. However, even if it is conservatively assumed that all consumed yeast-containing bread, rolls and fine pastry are fortified with the NFI at the maximum intended use levels, which deliver 5 µg vitamin D/100 g of these foods, it is highly unlikely that Tolerable Upper Intake Levels established by EFSA (EFSA NDA Panel, 2012) for children aged 1–10 years (50 µg/day) and adults (100 µg/day) are exceeded.

The applicant has not carried out any toxicological studies on the product to which the application applies. The Tolerable Upper Intake Levels for vitamin D were set by EFSA at 100 µg/day for adults and adolescents (10–18 years), at 50 µg/day for children (1–10 years) and at 25 µg/day for infants (up to 1 year) (EFSA, 2012). Given the source, nature and the intended uses of the NFI, the Panel considers that the absence of toxicological studies with the NFI is acceptable.

The Panel considers that the risk of allergic reactions to the NFI cannot be ruled out but is not dissimilar to the risk associated with conventional baker's yeast (*S. cerevisiae).*

The source for the production of the NFI is *S. cerevisiae*, an organism with a long history of safe food use. EFSA has categorised *S. cerevisiae* as a microorganism that has Qualified Presumption of Safety status. Treatment with UV is employed to induce the conversion of the endogenous ergosterol into vitamin D2. The NFI is intended for use in the production of yeast-leavened bread, rolls and fine

pastry and in food supplements. Even if the NFI is used at the maximum intended use levels, which deliver 5 µg vitamin D/100 g bread, rolls and fine pastry, it is highly unlikely that Tolerable Upper Intake Levels as established by EFSA (EFSA NDA Panel, 2012) will be exceeded.

The Panel considers that UV-treated baker's yeast exhibiting an enhanced content of vitamin D2 is safe under the intended conditions of use.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 4 May 2012, the company Lallemand SAS submitted a request under Article 4 of the Novel Food Regulation (EC) N° 258/97 to place on the market 'UV treated baker's yeast' as a novel food ingredient (NFI).

On 31 August 2012, the competent authorities of the United Kingdom forwarded to the Commission their initial assessment report, which came to the conclusion that the UV-treated baker's yeast exhibiting an enhanced content of vitamin D is acceptable as a novel food ingredient at the proposed uses and use levels.

On 11 September 2012, the Commission forwarded the initial assessment report to the other Member States. Several of the Member States submitted comments or raised objections.

The concerns of a scientific nature raised by the Member States can be summarised as follows:

- The product specifications should specify the maximum tachysterol content.
- The specifications of UVB including maximum radiation intensity used in the production of vitamin D-enriched yeast through UVB irradiation were requested.
- The applicant should provide information on possible effects of the UV treatment in the yeast and evaluate the presence of potential undesirable newly formed components resulting from yeast components, such as lipids and proteins. The specifications should include safe maximum levels for undesirable compounds.
- No data on ingredients other than tachysterol and ergosterol or comparative analyses with the untreated yeast were submitted.
- It would be useful if the company provided additional information on the stability of vitamin D2 in the finished products (food and food supplements).
- The intake estimate should consider the categories of bread consumed in Europe, including France, since categories mentioned in the application come from non-European states [North America].
- The doses of the NFI (mg/kg) added to the dough used to make bread(s) to reach the concentration of vitamin D2 indicated by the applicant should be clearly specified to avoid over-dosage of the ingredient by users.

Terms of reference as provided by the European Commission

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Food Safety Authority is asked to carry out the additional assessment for 'UV treated yeast' as a food ingredient in the context of Regulation (EC) N° 258/97.

EFSA is asked to carry out the additional assessment and to consider the elements of a scientific nature in the comments raised by the other Member States.

ASSESSMENT

In accordance with Commission Recommendation 97/618/EC, UV-treated baker's yeast has been allocated to Class 2.1, i.e. foods or food ingredients that are "*complex novel foods from non-GMO sources. The source of the novel food has a history of food use in the Community*". The assessment of the safety of this novel food ingredient (NFI) is based on data supplied in the original application, the initial assessment by the competent authority of the United Kingdom, the concerns and objections of the other Member States and the responses of the applicant. The data are required to comply with the information required for the novel foods of Class 2.1, i.e. structured schemes I, II, III, IX, XI, XII and XIII of Commission Recommendation 97/618/EC. In the text these structured schemes are numbered 1 to 7. It is noted that the NFI is intended by the applicant to be marketed as yeast (*Saccharomyces cerevisiae*) containing an enhanced level of vitamin D2 for addition to foods, i.e. yeast-leavened bread, rolls, fine pastry and food supplements. This assessment concerns only risk that might be associated with consumption, and is not an assessment of the efficacy of UV-treated baker's yeast with regard to any claimed benefit.

1. Specification of the Novel Food (NF)

The novel food ingredient (NFI) is baker's yeast (*Saccharomyces cerevisiae*) treated with UV to induce the conversion of ergosterol to vitamin D2 (ergocalciferol); the structures of the substances are shown in Figure 1. The applicant intends to use the NFI during the production of yeast-leavened bread, rolls and fine pastry and food supplements.

Vitamin D2:
Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol
Synonym: ergocalciferol
Chemical Abstract Service Registry Number: 50-14-6.
Molecular weight: 396.65 Da.

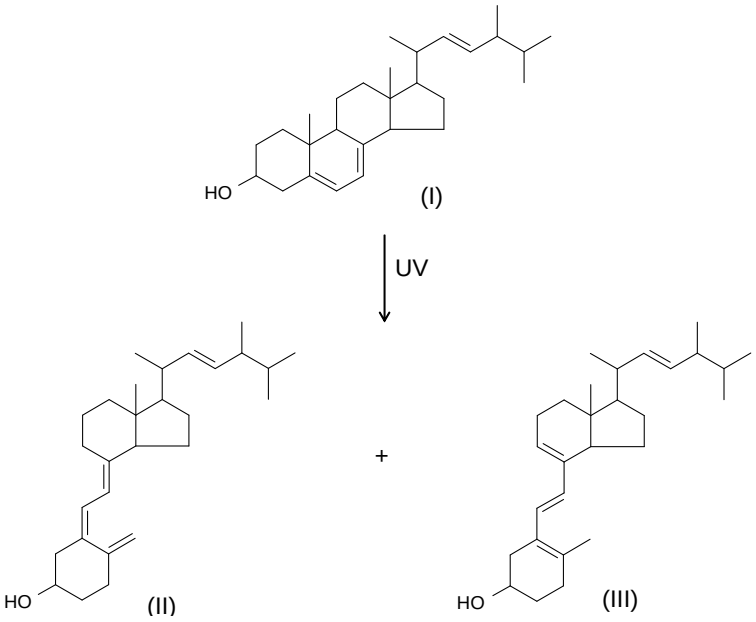

Figure 1: Structures of ergosterol (I), vitamin D2 (II) and tachysterol (III)

The specifications proposed by the applicant are given in Table 1.

Table 1: Specifications of the novel food ingredient

Parameters	Specification	Methods
Appearance	Tan-coloured, free-flowing granules	Visual
Vitamin D2	1 800 000–3 500 000 IU vitamin D/100 g [(a)] (450–875 µg/g)	Adapted AOAC method 982.29 (AOAC, 2000)
Coliforms	<1 000/g	FDA Bacteriological Analytical Manual
E. coli	<10/g	FDA Bacteriological Analytical Manual
Salmonella	Absent/25 g	FDA Bacteriological Analytical Manual

(a): 1 mg of vitamin D corresponds to 40 000 IU.

Data demonstrating the validation of the method employed for the quantification of vitamin D2 have been provided.

The vitamin D2 content in eight lots of the NFI ranged from 2 560 000 to 3 750 000 IU/100 g (640–940 µg/g); the average content of vitamin D2 in these lots was 3 065 417 IU/100 g, corresponding to 770 µg/g.

It is known that the UV-induced conversion of ergosterol into vitamin D2 is accompanied by photochemical isomerisations resulting in by-products such as tachysterol and lumisterol (Havinga et al., 1960); the structure of tachysterol is shown in Figure 1. Analogous products are known to be formed in the course of the UV-induced conversion of epidermal 7-dehydrocholesterol into vitamin D3 (Holick et al., 1981). The applicant, therefore, performed analyses to investigate the potential formation of these sterols under the conditions employed for the UV treatment of baker's yeast. The results of HPLC show that, apart from the intended vitamin D2, tachysterol was the only additional sterol detected by HPLC analysis. An external laboratory contracted by the applicant quantified the levels present in two commercial lots. Tachysterol levels were found to be 140 and 145 µg/g, and vitamin D2 levels were found to be 672 and 825 µg/g. All other minor peaks were also present prior to UV treatment. According to the applicant, the average amounts of vitamin D and tachysterol in the vitamin D2 yeast concentrate are 750 µg/g (30,000 IU) and 140 µg/g, respectively. Therefore, the production of a bread product containing 200 IU/100 g will require 6.67 mg of vitamin D2 yeast concentrate that contains 30 000 IU/g. The 6.67 mg of yeast concentrate will provide 0.93 µg of tachysterol/100 g of bread. Therefore, the Panel does not consider it necessary to include tachysterol in the product specification.

The Panel notes that UV irradiation may result in reactions of biomolecules, such as lipids or proteins. However, taking into account (i) the parameters of the UV treatment of baker's yeast as performed in the course of the production process of the NFI (e.g. the dimensions of the UV irradiation chamber, the flow rate of the yeast cream and the employed UV power), (ii) the low levels of potential reaction products that might be expected under these conditions from UV-induced reactions, e.g. oxidations of yeast lipids or proteins, and (iii) the intended use levels of the NFI, the Panel considers that it is not necessary to perform additional analyses for potential products formed from yeast components as a result of the UV treatment.

Analysis of three lots of vacuum-packed vitamin D2 yeast concentrate indicated that there was no significant reduction in the level of vitamin D2 over a three-year period. In response to a request by Member States, the applicant provided data on the vitamin D2 content in eight samples of two different bread types (four white bread, four wholewheat bread) after 4 and 14 days of storage and compared the contents of vitamin D2 in the four dough formulations. One of each of the bread types was produced with untreated baker's yeast. These results indicate that no significant vitamin D2

loss occurred during the bread-making process, including baking at 227 °C and storage of the bread for at least 14 days.

The applicant also provided data on the stability of vitamin D2 in two batches of a food supplement stored at 4 °C, 25 °C and 30 °C for 24 months. The data suggest minimal, if any, loss of vitamin D2 over this period.

The Panel considers that the provided compositional data, the specification, the data from batch testing and the stability of the NFI are sufficient and do not give rise to safety concerns.

2. Effect of the production process applied to the NFI

The applicant has a long experience in producing baker's yeast. Details of the commercially performed fermentation, critical process parameters and quality assurance measures have been provided.

The yeast cream resulting from the fermentation step is continuously pumped past UV lamps (254 nm) for a certain period of time. The applicant provided information on the dimensions of the UV irradiation chamber and the electrical cabinet, the flow rate of the yeast cream and the employed UV power. The applicant did not provide information on the maximum UV irradiation power applied; however, the Panel considers the information provided by the applicant in response to the Member State comment on UV treatment conditions to be sufficient. The UV treatment step is followed by drying using a fluid bed dryer (yeast for baking) or a spray dryer or roller dryer (yeast for supplements). The resulting "vitamin D2 yeast concentrate" contains between 1 800 000 IU/100 g and 3 500 000 IU/100 g vitamin D2, compared with the initial concentration of less than 20 IU vitamin D2/100 g. When used for baking, this concentrate would be blended with conventional yeast in order to adjust the intended amount of vitamin D2 in the final product.

All production steps are certified according to the International Organization for Standardization (ISO) and operated in accordance with Good Manufacturing Practice (GMP).

Each production lot of the concentrate is analysed by an external laboratory regarding the content of vitamin D2. Microbiological analyses are performed in-house following internationally recognised methods. Certificates of analysis have been provided for three batches, all complying with the product specifications.

UV radiation at a wavelength of 254 nm, as used in this process, will induce mutations in DNA in surviving cells, albeit in very low numbers. The applicant used RAPD-PCR (randomly amplified polymorphic DNA) and RFLP (restriction fragment length polymorphism) DNA fingerprinting techniques to screen for chromosomal rearrangements and point mutations in the UV-treated baker's yeast. These methods did not reveal differences between the UV-treated yeast and the control (Bertrand, 2010).

The Panel considers that, although the UV treatment may result in mutations in the employed baker's yeast, their low numbers, the conditions of the process and the intended uses of the NFI would not allow mutants to become dominant in the final product.

According to the applicant, the UV-treated baker's yeast retains its baking activity; however, no experimental data were provided.

The Panel concludes that the data provided on the production process are sufficient and do not give rise to safety concerns.

3. History of the organism used as a source

Saccharomyces cerevisiae has an extensive history of food use in the baking and brewing industries. EFSA has categorised *S. cerevisiae* as a microorganism that has QPS (Qualified Presumption of Safety) status (EFSA BIOHAZ Panel, 2013).

4. Anticipated intake/extent of the use of the NF

The applicant intends to use the NFI as an alternative source for vitamin D for fortification in foods which contain yeast and for food supplements. The original dossier suggested that the NFI be added at use levels which provide 5 µg vitamin D2 per 100 g of various bread types such as white bread, wholemeal bread, brown, granary and wheatgerm bread and other yeast-leavened breads. The applicant indicated that bread will be formulated by using blends of UV-treated and untreated baker's yeast to ensure that, irrespective of the level of vitamin D2 present in individual batches of the yeast concentrate, it would contain a maximum of 5 µg vitamin D2 (200 IU) per 100 g. Based on the specification (Table 1), 5 µg of vitamin D2 is equivalent to between 5.7 and 11 mg of the UV-treated yeast. The intended use levels for the NFI in food supplements would deliver 5 µg vitamin D2 per day.

The original dossier contained intake estimates based on UK NDNS data only for bread fortified with the NFI. According to these data, the mean and P97.5th percentile intake estimates for children (with an age of 4–18 years) would be 3.6 and 8.6 µg/day, respectively, if all consumed bread was fortified with the NFI; for adults vitamin D intakes from fortified bread would be 4.5 and 10.8 µg/day, respectively.

During the evaluation by EFSA, the applicant requested that this NFI also be authorised for use for fortification of yeast-leavened rolls and yeast-leavened fine pastry at maximum concentrations of 5 µg vitamin D2 per 100 g of these foods. At the request of EFSA, the applicant therefore provided an intake estimate which covers also potential intakes from yeast-leavened rolls and yeast-leavened fine pastry. The applicant used the chronic food consumption statistics of the EFSA Comprehensive Food Consumption Database.[4] Because this database does not include "yeast-leavened fine pastry", the applicant conservatively estimated intakes for the broader, superordinate level 2 category "fine bakery wares". "Rolls" are covered by the level 2 food category "bread and rolls" in the published chronic food consumption statistics of the EFSA Comprehensive Food Consumption Database.

Table 2 (all subjects) and Table 3 (consumers only) provide combined daily intake estimates for the two level 2 food categories "bread and rolls" and "fine bakery wares" and for vitamin D2 from these foods fortified with the NFI (Appendix).

The highest 97.5 percentile for among EU Member States was obtained for "other children" (4-10 years; 27.2 µg/day) and adults (36.0 µg/day) from Latvia and adolescents from Germany (35.5 µg/day).

Regarding food supplements, the applicant considers the use of the NFI in food supplements as a direct "like for like" replacement for existing vitamin D2 ingredients and, as such, will not significantly add to the level of vitamin D consumed by individuals via supplements. The use level of the NFI intended by the applicant for food supplements is 5 µg/day.

Vitamin D intakes from the diet

In 2012, EFSA estimated that the mean percentile intake of vitamin D from foods among young children varies from 1.7 µg/day (Denmark, boys, 1–3 years) to 5.6 µg/day (Greece, 1.5 years) while the high percentile intake estimates vary from 2.4 µg/day (Denmark, 95th percentile, boys, 1–3 years) to 11.9 µg/day (Greece, 90th percentile, 1–5 years) (EFSA NDA Panel, 2012).

[4] http://www.efsa.europa.eu/en/datexfooddb/docs/datexfooddbchronicgday.xls

In adolescents, mean intake from foods varies from 1.6 µg/day (Spain, 11–17 years) to 4.0 µg/day (Belgium, boys 13–18 years). Intakes at the 95th percentile were between 3.0 µg/day (Spain, 11–17 years) and 7.7 µg/day (Italy, boys, 10 to < 18 years, including fortified food). Mean or median intakes from foods and supplements and for the 95th percentile of consumption are within these ranges.

For adults, estimates of mean intake vitamin D from foods varied from 1.1 µg/day (Spain, women, 18–64 years) to 8.2 µg/day (Finland, men, 2–74 years) and estimated 95th percentile intakes varied from 2.4 µg/day (Spain, women, 1–64 years) to 16.0 µg/day (Finland, men, 25–74 years). For those adults who consume vitamin D also from food supplements, intakes were estimated to be 1.5-fold higher.

The Panel notes that the type of intake estimate provided by the applicant assumes that all consumed food products within a food category contain the ingredient at the maximum specified level of use. It is also noted that the combined high percentile intake from the two level 2 food categories (breads and rolls and fine bakery wares) based on summary statistics is expected to over-estimate intakes. Third, among the level 2 food category "fine bakery wares" the applicant intends to use the NFI only in "yeast-leavened fine pastry", but the intake estimate is based on intakes for the complete level 2 category "fine bakery wares", although many products in this category do not contain yeasts. The Panel therefore considers that the applicant's intake estimate significantly over-estimates intakes. However, even if it is conservatively assumed that all consumed yeast-containing bread, rolls and fine pastry are fortified with the NFI at the maximum intended use levels, which deliver 5 µg vitamin D/100 g of these foods, it is highly unlikely that tolerable upper intake levels established by EFSA (EFSA NDA Panel, 2012) for children aged 1–10 years (50 µg/day) and adults (100 µg/day) will be exceeded.

5. Information from previous exposure to the NF or its source

Both the source of the NFI, i.e. *S. cerevisiae*, and vitamin D2 have a long history of food use. In Canada, the addition of vitamin D2-yeast to yeast-leavened bakery products has been permitted at a level of up to 90 IU (2.25 µg) per 100 g of product (Health Canada, 2011). In the USA, the food additive regulations have been amended to allow for the safe use of vitamin D2 baker's yeast in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D2 per 100 g of the finished food (FDA, 2012).

6. Nutritional information on the NF

Bioavailability of vitamin D2 from bread prepared with the NFI has been investigated in a feeding study with growing, vitamin-deficient rats. Plasma 25-hydroxyvitamin D (25OHD) levels increased in a dose-dependent manner, but rats fed the bread baked with the vitamin D2-enriched yeast achieved lower levels than rats fed vitamin D3 (Hohmann et al., 2011). According to a PowerPoint presentation on a four-week trial (carried out in 13 women) provided by the applicant, bread baked with vitamin D2-containing yeast had a comparable effect on plasma serum 25OHD concentration as a vitamin D2-containing supplement (Lamberg-Allardt et al., 2010).

The bioavailability of vitamin D2 from irradiated mushrooms, in which vitamin D2 is formed from endogenous ergosterol in an analogous way to that seen in the UV-treated baker's yeast, has also been demonstrated in feeding studies with rats using the serum level of 25-hydroxyvitamin D as indicator (Jasinghe et al., 2005; Koyyalamudi et al., 2009).

The Panel notes that current dietary reference values for children aged 1–18 years and for adults vary from 5 to 15 µg/day and from 10 to 20 µg/day, respectively (SCF, 1993; IoM, 2011; DACH, 2013; NNR, 2013).

The Panel considers that the NFI is not nutritionally disadvantageous. The Panel notes that high percentile intakes estimates provided by the applicant at the proposed uses and use levels exceed current international dietary references values for vitamin D.

7. Microbiological information on the NF

According to the applicant, every batch of the NFI will be tested to ensure that it meets the microbiological standards and specifications. The Panel considers that the data provided do not give rise to concerns with regard to the microbiological quality of the NI.

8. Toxicological information on the NF

The applicant has not carried out any toxicological studies on the product to which the application applies.

The Tolerable Upper Intake Levels for vitamin D were set by EFSA at 100 µg/day for adults and adolescents (10–18 years), at 50 µg/day for children (1–10 years) and at 25 µg/day for infants (up to 1 year) (EFSA NDA Panel, 2012).

Given the source, nature and the intended uses of the NFI, the Panel considers that the absence of toxicological studies with the NFI is acceptable.

9. Allergenicity

The Panel considers that the risk of allergic reactions to the NFI cannot be ruled out but is not dissimilar to that associated with conventional baker's yeast (*S. cerevisiae*).

10. Discussion

The source for the production of the NFI is *S. cerevisiae*, an organism with a long history of safe food use. EFSA has categorised *S. cerevisiae* as a microorganism that has QPS status. Treatment with UV irradiation is employed to induce the conversion of the endogenous ergosterol into vitamin D2. Owing to the nature of the source and the conditions of the manufacturing process, the provided compositional data and the proposed specification of the NFI are considered sufficient and do not give rise to safety concerns.

The NFI is intended for use in the production of yeast-leavened bread, rolls and fine pastry and in food supplements. The Panel notes that high percentile intakes estimates provided by the applicant at the proposed uses and use levels exceed current international dietary references values for vitamin D. However, even if the NFI is used at the maximum intended use levels, which deliver 5 µg vitamin D/100 g bread, it is highly unlikely that Tolerable Upper Intake Levels as established by EFSA (EFSA NDA Panel, 2012) are exceeded.

CONCLUSIONS

The Panel considers that UV-treated baker's yeast exhibiting an enhanced content of vitamin D2 is safe under the intended conditions of use.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier 'Application for the Approval of Vitamin D2 Yeast Concentration)' under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients" received on 14/02/2013. Submitted by Lallemand. Additional data were provided on 28/11/2013 and 02/12/2013.

2. Letter from the European Commission to the European Food Safety Authority with the request for an opinion on the safety of 'UV treated yeast', received on 05/04/2013; Ref. Ares (2013)542120 – 04/04/2013.

3. Initial assessment report carried out by the Food Safety Authority of the United Kingdom: 'UV treated Baker's yeast'.

4. Member States' comments and objections.

Response by the applicant to the initial assessment report and the Member States' comments and objections.

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APPENDIX

Table 2: Combined daily intake estimates for foods in the two level 2 food categories "bread and rolls" and "fine bakery wares" and for vitamin D2 from the NFI for "all subjects"

Country	Age class	No of subjects	Mean consumption (g)	P97.5 consumption (g)	Mean consumption of vitamin D2 (μg)	P97.5 consumption of vitamin D2 (μg)
Belgium	Adolescents	584	183.9	517.5	9.2	25.9
	Adults	1304	174.4	530.5	8.7	26.5
	Toddlers	36[(a)]	109.9	286.5	5.5	14.3
	Other children [(b)]	625	113.4	266.5	5.7	13.3
Bulgaria	Toddlers	428	101.0	262.5	5.0	13.1
	Other children	433	143.5	373.5	7.2	18.7
Cyprus	Adolescents	303	117.0	296.7	5.8	14.8
Czech Republic	Other children	389	141.4	359.0	7.1	17.9
	Adolescents	298	207.9	575.0	10.4	28.8
	Adults	1 666	222.8	664.0	11.1	33.2
Germany	Adolescents	1 011	184.3	650.0	9.2	32.5
	Adults	10 419	194.8	599.0	9.7	30.0
	Toddlers	84	57.2	152.3	2.9	7.6
	Other children	223	118.2	295.7	5.9	14.8
Denmark	Other children	490	146.8	314.4	7.3	15.7
	Adolescents	479	151.1	335.0	7.6	16.8
	Adults	2 822	169.2	367.0	8.5	18.4
Spain	Adults	410	134.0	436.7	6.7	21.8
	Adolescents	86	170.2	552.8	8.5	27.6
	Adults	981	133.9	407.8	6.7	20.4
	Toddlers	17 [(a)]	51.7	194.5	2.6	9.7
	Other children	156	119.4	365.0	6.0	18.3
	Adolescents	209	194.1	599.5	9.7	30.0
	Other children	399	139.9	328.5	7.0	16.4
	Adolescents	651	189.0	492.0	9.4	24.6
Finland	Adults	1 575	2.2	15.5	0.1	0.8
	Toddlers	497	2.3	18.3	0.1	0.9
	Other children	250	129.4	347.3	6.5	17.4
France	Other children	482	118.1	329.0	5.9	16.4
	Adolescents	973	157.2	445.6	7.9	22.3
	Adults	2 276	167.8	484.6	8.4	24.2
United Kingdom	Adults	1 724	158.9	402.9	7.9	20.1
Greece	Other children	839	105.3	295.0	5.3	14.8
Hungary	Adults	1 074	164.7	427.3	8.2	21.4
Ireland	Adults	958	176.4	445.1	8.8	22.3
Italy	Toddlers	36	49.1	245.1	2.5	12.3
	Other children	193	125.1	367.0	6.3	18.4
	Adolescents	247	160.3	478.4	8.0	23.9
	Adults	2 313	144.4	422.1	7.2	21.1
Latvia	Other children	189	129.9	493.0	6.5	24.7
	Adolescents	470	176.7	622.5	8.8	31.1
	Adults	1 306	193.9	685.0	9.7	34.3

Country	Age class	No of subjects	Mean consumption (g)	P97.5 consumption (g)	Mean consumption of vitamin D2 (μg)	P97.5 consumption of vitamin D2 (μg)
Netherlands	Adults	750	203.7	535.0	10.2	26.8
	Toddlers	322	102.8	264.0	5.1	13.2
	Other children	957	128.7	328.7	6.4	16.4
Sweden	Adults	1 210	159.0	387.9	8.0	19.4
	Other children	1 473	110.7	302.8	5.5	15.1
	Adolescents	1 018	119.6	331.5	6.0	16.6

(a): As the number of subjects is lower than 60, the 95th and higher percentiles may not be statistically robust.
(b): "Other children" comprises children aged 4 to 10 years.

Table 3: Combined daily intake estimates for foods in the two level 2 food categories "bread and rolls" and "fine bakery wares" and for vitamin D2 from the NFI for "consumers only"

Country	Age class	No of consumers	Mean consumption (g)	P97.5 consumption (g)	Mean consumption of vitamin D2 (μg)	P97.5 consumption of vitamin D2 (μg)
Belgium	Adolescents	567	205.0	522.6	10.2	26.1
Belgium	Adults	1262	201.0	545.0	10.0	27.3
Belgium	Toddlers	36 [(a)]	110.7	286.5	5.5	14.3
Belgium	Other children	624	117.5	267.7	5.9	13.4
Bulgaria	Toddlers	408	111.7	266.1	5.6	13.3
Bulgaria	Other children	417	157.0	376.5	7.8	18.8
Cyprus	Adolescents	296	132.7	311.0	6.6	15.6
Czech Republic	Other children	387	152.6	359.0	7.6	17.9
Czech Republic	Adolescents	297	222.2	580.0	11.1	29.0
Czech Republic	Adults	1 648	255.0	684.0	12.7	34.2
Denmark	Other children	490	155.5	331.6	7.8	16.6
Denmark	Adolescents	479	161.6	353.6	8.1	17.7
Denmark	Adults	2 822	178.4	384.2	8.9	19.2
Finland	Toddlers	182	7.1	27.0	0.4	1.4
Finland	Adults	549	10.7	28.0	0.5	1.4
Finland	Other children	250	131.4	347.3	6.6	17.4
France	Other children	469	119.7	329.0	6.0	16.4
France	Adolescents	959	161.0	446.0	8.1	22.3
France	Adults	2 253	177.0	487.4	8.9	24.4
Germany	Toddlers	81	65.8	155.0	3.3	7.8
Germany	Other children	223	125.8	296.7	6.3	14.8
Germany	Adolescents	991	223.9	710.0	11.2	35.5
Germany	Adults	10 223	230.1	641.0	11.5	32.1
Greece	Other children	791	114.8	300.7	5.7	15.0
Hungary	Adults	1 071	192.3	460.7	9.6	23.0
Ireland	Adults	956	180.0	445.9	9.0	22.3
Italy	Toddlers	25 [(a)]	79.9	245.1	4.0	12.3
Italy	Other children	184	136.9	367.0	6.8	18.4
Italy	Adolescents	243	169.7	495.4	8.5	24.8
Italy	Adults	2 256	159.5	436.5	8.0	21.8
Latvia	Other children	178	164.9	543.0	8.2	27.2
Latvia	Adolescents	453	214.3	635.0	10.7	31.8
Latvia	Adults	1 267	242.6	720.0	12.1	36.0
Netherlands	Adults	743	220.6	545.0	11.0	27.3
Netherlands	Toddlers	322	105.7	264.0	5.3	13.2
Netherlands	Other children	955	132.9	330.7	6.6	16.5
Spain	Adults	393	159.2	472.5	8.0	23.6
Spain	Adolescents	85	181.8	562.8	9.1	28.1
Spain	Adults	953	149.6	421.7	7.5	21.1
Spain	Other children	396	146.4	329.0	7.3	16.5
Spain	Adolescents	648	201.0	509.5	10.0	25.5
Spain	Toddlers	13 [(a)]	69.6	194.5	3.5	9.7
Spain	Other children	148	138.1	365.0	6.9	18.3
Spain	Adolescents	206	209.8	672.5	10.5	33.6
Sweden	Adults	1 210	163.8	395.7	8.2	19.8

Country	Age class	No of consumers	Mean consumption (g)	P97.5 consumption (g)	Mean consumption of vitamin D2 (μg)	P97.5 consumption of vitamin D2 (μg)
Sweden	Other children	1 463	116.4	304.0	5.8	15.2
Sweden	Adolescents	1 013	130.6	339.0	6.5	17.0
United Kingdom	Adults	1 706	164.7	408.3	8.2	20.4

(a): As the number of subjects is lower than 60, the 95th and higher percentiles may not be statistically robust.
(b): "Other children" comprises children aged 4 to 10 years.

ABBREVIATIONS

bw	body weight
GMO	genetically modified organism
NF(I)	Novel Food (Ingredient)
NOAEL	no observed adverse effect level
SCF	Scientific Committee on Food